

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

CVS PHARMACY, INC.,  
RITE AID CORPORATION and  
RITE AID HDQTRS. CORP.,

Plaintiffs,

vs.

ABBVIE INC.; ALLERGAN, INC.;  
ALLERGAN SALES, LLC; ALLERGAN  
USA, INC.; FOREST LABORATORIES,  
INC.; FOREST LABORATORIES  
HOLDINGS, LTD.; FOREST  
LABORATORIES IRELAND, LTD.;  
FOREST LABORATORIES, LLC; HETERO USA  
INC.; HETERO LABS LTD.; HETERO DRUGS  
LTD.; TORRENT PHARMACEUTICALS LTD.;  
TORRENT PHARMA INC.; ALKEM  
LABORATORIES LTD.; ASCEND  
LABORATORIES, LLC; INDICHEMIE HEALTH  
SPECIALTIES PRIVATE LTD.; GLENMARK  
GENERICS INC., USA; GLENMARK  
GENERICS LTD.; GLENMARK  
PHARMACEUTICALS LTD.; AMERIGEN  
PHARMACEUTICALS, INC.; AMERIGEN  
PHARMACEUTICALS, LTD.; WATSON  
LABORATORIES, INC. (NV); WATSON  
LABORATORIES, INC. (DE); WATSON  
LABORATORIES, INC. (NY); WATSON  
LABORATORIES, INC. (CT); WATSON  
PHARMA, INC.; WATSON  
PHARMACEUTICALS, INC.; ACTAVIS, INC.;  
TEVA PHARMACEUTICAL INDUSTRIES  
LTD.; and TEVA PHARMACEUTICALS USA,  
INC.,

Defendants.

CASE NO. 1:20-cv-10087

JURY TRIAL DEMANDED

**COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs CVS Pharmacy, Inc., Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (“Plaintiffs”) sue Defendants AbbVie Inc. (“AbbVie”); Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, “Allergan”); Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd. (collectively, “Forest”); Hetero USA Inc., Hetero Labs Ltd. and Hetero Drugs Ltd. (collectively “Hetero”); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively “Torrent”); Alkem Laboratories Ltd. and Ascend Laboratories, LLC (“Alkem”); Indchemie Health Specialties Private Ltd. (“Indchemie”); Glenmark Generics Inc., USA, Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd. (collectively “Glenmark”); Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. (collectively “Amerigen”); and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Actavis, Inc., Watson Pharma, Inc., Watson Pharmaceuticals, Inc., Teva Pharmaceuticals Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively “Watson”), for Defendants’ violations of the antitrust laws relating to the pharmaceutical drug Bystolic (nebivolol hydrochloride) (“Bystolic”). For their Complaint, Plaintiffs allege as follows:

**I. INTRODUCTION**

1. This is a civil antitrust action seeking treble damages and other relief arising out of the Defendants’ unlawful exclusion of generic substitutes for the branded drug Bystolic, otherwise known as nebivolol hydrochloride or nebivolol HCl, a “beta blocker” used to treat high blood pressure. Forest and its successors, Allergan and AbbVie (collectively the “Brand Defendants”), manufacture and sell Bystolic which generates annual sales of more than \$500 million in the United States. Although would-be generic manufacturers began filing Abbreviated New Drug Applications (“ANDAs”) with the United States Food and Drug Administration (the

“FDA”) to market generic nebivolol HCl on December 17, 2011,<sup>1</sup> no generic competitor has entered or will enter until September 17, 2021.

2. The only material difference between generic and brand name drugs is their price. Generics are at least 20% cheaper than their branded counterparts when only one generic is on the market and at least 50% cheaper when there are multiple generic competitors on the market. As a result, generics constitute both (a) an opportunity for drug purchasers to obtain enormous cost savings and (b) a serious threat to the monopoly power and profits of the manufacturer of the corresponding brand name drug. Due to their lower price, AB-rated generics typically take 80% or more of the sales of a drug molecule from the brand name product within six months of generic entry. These extremely rapid erosion rates of the brand manufacturer’s sales are encouraged by state drug substitution laws, which permit (and in some cases require) dispensing pharmacies like the ones owned and operated by Plaintiffs to substitute available AB-rated generic drugs for a brand drug unless the prescribing physician specifically orders otherwise (by indicating that the drug should be “dispensed as written” or its equivalent).

3. Acutely aware of these realities, Forest (and its successors) engineered a series of unlawful reverse-payment deals (also known as “pay for delay” deals) with each of its would-be generic competitors, specifically, Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen and Watson (collectively, the “Generic Defendants”). From October 2012 through November 2013, Forest entered into these serial deals pursuant to which each generic (1) agreed not to compete with Forest or enter the market prior to September 17, 2021, unless another generic competitor entered the market earlier; and in exchange (2) received “side-deals,” and cash payments, the

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<sup>1</sup> See, e.g., 11/27/2015 Letter from Food and Drug Administration (“FDA”) to Watson, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203683Orig1s000Ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf).

precise amounts of which have not been publicly disclosed except that they each exceed \$15,000,000 in value. As corporate successors to Forest, Allergan and then AbbVie have continued this illegal collusion and unreasonable restraint of trade in the market for nebivolol HCl, all at the expense of purchasers. Every month of delayed generic competition has allowed Forest and its successors to unlawfully maintain many millions of dollars in monopoly profits from Bystolic that it would have otherwise lost to the Generic Defendants in the absence of Forest's large and unjustified payments to the Generic Defendants to delay generic Bystolic.

4. Beginning on December 17, 2011,<sup>2</sup> after the Generic Defendants became the first generic manufacturers to seek approval from the FDA to market generic Bystolic, Forest sued each of them, accusing them of allegedly infringing U.S. Patent No. 6,545,040 (the "'040 Patent"), which Forest submitted for listing in the FDA Orange Book by certifying that the patent covered Bystolic. These suits, filed in mid-March 2012, automatically triggered stays of FDA approval of the generic products (meaning that regardless of the merits of the patent infringement actions, the FDA could not finally approve any of the Generic Defendants to launch generic Bystolic before June 18, 2015 absent an earlier favorable decision for the Generic Defendants or a dismissal of the actions). Foreclosing the Generic Defendants from launching also foreclosed all other generic manufacturers of Bystolic. As the first manufacturers to file for approval of generic Bystolic, the Generic Defendants were eligible to share 180 days of market exclusivity during which no other generic Bystolic product could be sold (other than a generic marketed

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<sup>2</sup> See, e.g., 11/27/2015 Letter from FDA to Watson, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203683Orig1s000Ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf); 5/27/2017 Letter from FDA to Glenmark, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2017/203821Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf); 6/24/2015 Letter from FDA to Alkem, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203741Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf).

under Forest's approved NDA, known as an "authorized generic").

5. Between March 2012 and November 2013, while the stays were in effect, the Generic Defendants defended the patent infringement suits and prepared to bring their generic Bystolic products to market to compete with Forest's branded Bystolic. At least six of the seven Generic Defendants would have been ready to launch well before September 17, 2021, as each had final FDA approval to do so as set forth in the table below:

Manufacturer	ANDA No.	Final Approval Date
Amerigen	203659	4/16/15
Watson	203683	11/27/15
Alkem	203741	6/24/15
Glenmark	203821	5/25/17
Indchemie	203828	7/29/15
Torrent	203966	3/2/18

6. The Generic Defendants would have succeeded in the patent litigation because the '040 Patent was weak. The '040 Patent litigation likely would have concluded by mid-2015, including all appeals. The Generic Defendants would have won and launched by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic, U.S. Patent No. 5,759,580 (the "'580 Patent"), or (b) the date their ANDAs were finally approved. Rather than risk facing competition from the Generic Defendants as early as June 2015 and the subsequent reduction in Bystolic brand sales and revenues such competition would cause, Forest paid each of the Generic Defendants to stay off of the market until September 21, 2021.

7. The side-deals that Forest provided to each Generic Defendant were intended to shield Forest from the risk of competition, and the Generic Defendants readily accepted these exclusionary side-deals to quit the patent fight.

8. On February 18, 2014, Actavis PLC and Forest announced an equity and cash merger.<sup>3</sup> On March 1, 2014, Forest’s outside lawyers at Weil, Gotshal & Manges LLP were reviewing Forest’s documents as part of their “work on the Actavis merger agreement.”<sup>4</sup> On March 4, 2014, Forest’s outside lawyers informed Forest in-house counsel Eric Agovino via email (the “Agovino email”) that “[b]efore we engage in any discussions with the FTC . . . we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements *as well as the side agreements with those generic companies.*”<sup>5</sup> Agovino replied:

“We entered into settlement agreements with the following defendants:

- 1) Hetero
- 2) Torrent
- 3) Alkem
- 4) Indchemie
- 5) Glenmark
- 6) Amerigen
- 7) Actavis [Watson’s successor]

*All had side-deals* (one was struck with Alkem, which is a related company with Indchemie).”<sup>6</sup>

9. Forest’s Agreement and Plan of Merger with Actavis PLC (the “Merger

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<sup>3</sup> See Actavis to Acquire Forest Laboratories, Inc. for ~\$25 Billion in an Equity and Cash Transaction, <https://www.businesswire.com/news/home/20140218005877/en/Actavis-Acquire-Forest-Laboratories-25-Billion-Equity>.

<sup>4</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-44 at 332).

<sup>5</sup> *Id.* (emphasis added).

<sup>6</sup> *Id.* (emphasis added).

Agreement”), dated February 17, 2014, provides additional details. Specifically, in the Merger Agreement, Forest disclosed its “material contracts,” which are defined to include “any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of \$15,000,000 or (y) impose monitoring or reporting obligations to [*sic*] any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied.”<sup>7</sup>

10. Forest listed each of the side-deals as a “material contract” “in connection with the settlement of BYSTOLIC patent dispute.”

11. Thus, Forest described each of the side-deals set forth below as a “material contract,” *i.e.*, a “Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of \$15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied.” The respective contracts are identified below.

12. **Hetero**: “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012 . . . together with the FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>8</sup>

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<sup>7</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

<sup>8</sup> *Id.* at 179.

13. **Torrent:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012 . . . together with the PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd. and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>9</sup>

14. **Alkem/Indchemie:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute. AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT was executed on January 9, 2013” and “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>10</sup>

15. **Glenmark:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012 . . . together with the COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories

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<sup>9</sup> *Id.*

<sup>10</sup> *Id.*



Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>11</sup>

16. **Amerigen:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013 . . . together with the BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute.”<sup>12</sup>

17. **Watson:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013 . . . together with (a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between Actavis, Inc. and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute.”<sup>13</sup>

18. Forest listed the side-deals in the Merger Agreement because, on information and belief, they “involve payments after the date [t]hereof of consideration in excess of \$15,000,000.”

19. As Forest publicly acknowledged in the Agovino email, and in the Merger Agreement, the side-deals were part and parcel of Forest’s patent settlement agreements with the

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<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 180.

<sup>13</sup> *Id.*

Generic Defendants in the Bystolic patent litigation, not stand-alone or independent agreements.

20. In addition to the consideration Forest provided each Generic Defendant in the form of a side-deal, Forest “agreed to reimburse certain of the Settling Defendants’ legal costs in connection with the patent litigation.”<sup>14</sup>

21. Forest also disclosed that its settlement agreements with the Generic Defendants “provide[d] a license to each of the Settling Defendants that will permit them to launch their respective generic versions of Bystolic as of the date that is the later of (a) three calendar months prior to the expiration of the ’040 patent, including any extensions and/or pediatric exclusivities or (b) the date that each Settling Defendant receives final FDA approval of its ANDA, ***or earlier in certain circumstances.***”<sup>15</sup> The bolded language typically refers to what is known as a “contingent launch provision” (“CLP”), or an “acceleration clause.” CLPs ensure a settling generic that it will not be competitively disadvantaged should a later settling generic negotiate an earlier licensed entry date or otherwise come to market earlier: pursuant to CLPs, the entry date may be “accelerated” permitting the settling generic to enter the market at the same time as any of its competitors. CLPs ensure settling generic ANDA filers that, if any other ANDA filer somehow makes it to market before the agreed-upon licensed entry date, that ANDA filer’s licensed entry date would be accelerated so that it could launch at the same time.

22. When CLPs are used, they generally operate the same way in each ANDA filer’s settlement agreement. Under a CLP, the first-filing ANDA filer (or, as here, filers) obtains protection from other first filers by agreeing to delay the launch of its generic products from the

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<sup>14</sup> <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>.

<sup>15</sup> *Id.* (emphasis added).

date of settlement until a date certain (here, exactly three months before the expiration of the '040 Patent),<sup>16</sup> but *if and only if* all other first-filer generic companies follow suit. By brokering the agreements, Forest ensured that, without regard to the strength of the Generic Defendants' challenges to the '040 Patent, Bystolic would have no generic competition, and Forest would maintain patent-generated monopoly profits until at least September 17, 2021.

23. Reverse-payment agreements like the side-deals in this case delay the entry date for generic drug products beyond the date when competition would otherwise begin. As the Third Circuit Court of Appeals put it, “when the parties’ settlement includes a [payment], the generic also presumably agrees to an early entry date [before patent expiration] that is later than it would have otherwise accepted.” *King Drug Co. of Florence, Inc. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015). Thus, absent the unlawful reverse payments, Forest and the Generic Defendants would have instead agreed upon an earlier licensed entry date for generic Bystolic. And, because of the CLPs, if *just one* of the Generic Defendants did not take an unlawful payment, and instead insisted on an earlier entry date untainted by a side-deal, *every other* Generic Defendant would enter on the same earlier date.

24. In sum, but for the anticompetitive reverse payments, reasonable companies in the position of the Generic Defendants would have launched their generic products earlier than September 17, 2021 either: (a) at risk; (b) upon prevailing against Forest in the underlying patent litigation; or (c) via lawful settlement agreements providing for earlier negotiated entry dates untainted by the delay caused by the unlawful reverse payments.

25. Had any of the above scenarios played out absent the unlawful reverse payments,

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<sup>16</sup> *Id.*

Plaintiffs would have paid substantially less for their requirements of nebivolol HCl.

26. Defendants' conduct was designed to, did, and continues to: (a) delay the entry of less expensive, AB-rated generic Bystolic; (b) fix, raise, maintain or stabilize the price of nebivolol HCl; and (c) allocate 100% of the United States market for nebivolol HCl to Forest and its successors until three months before expiration of the '040 Patent.

27. Defendants' monopoly power in the nebivolol HCl market was maintained through willful exclusionary conduct, as distinguished from a superior product, business acumen, or historical accident.

28. As alleged in greater detail below, Defendants' scheme to delay generic competition violated sections 1 and 2 of the Sherman Act, injuring Plaintiffs (and their assignors) and causing Plaintiffs (and their assignors) to pay overcharges on their purchases of branded (and eventually generic) Bystolic.

## **II. PARTIES**

29. Plaintiff CVS Pharmacy, Inc. ("CVS") is a Rhode Island corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 9,900 drugstores, approximately eleven mail service pharmacies, and twenty-seven specialty pharmacies owned and operated by its affiliates. CVS brings this Action on its own behalf and as the assignee of McKesson Corporation and Cardinal Health, Inc., which during the relevant period each purchased Bystolic directly from Defendants for resale to CVS and has expressly assigned its claims arising out of those purchases to CVS.

30. Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (collectively, "Rite Aid") are corporations organized and existing under the laws of the State of Delaware with a

principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public. Rite Aid brings this Action on its own behalf and as the assignee of McKesson Corporation, which during the relevant period purchased Bystolic directly from Defendants for resale to Rite Aid and has expressly assigned its claims arising out of those purchases to Rite Aid.

31. Defendant Forest Laboratories, Inc. is a Delaware corporation having its principal place of business at 909 Third Avenue, New York, NY 10022. The negotiation, execution and enforcement of the unlawful reverse payments challenged herein all took place from Forest Laboratories, Inc.'s New York, NY principal place of business.

32. Defendant Forest Laboratories Ireland, Ltd. is an Irish Corporation having a place of business at Clonsaugh Industrial Estate, Dublin 17, Ireland.

33. Defendant Forest Laboratories Holdings, Ltd. is a Bermudian corporation having a principal place of business at 18 Parliament Street, Hamilton HM 11, Bermuda. In or around February 2006, Defendant Forest Laboratories Ireland, Ltd. changed its name to Forest Laboratories Holdings, Ltd. and changed its corporate residence from Ireland to Bermuda.

34. Defendant Forest Laboratories, LLC is a Delaware limited liability company having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On July 1, 2014, in a series of transactions, Forest Laboratories, Inc. became a limited liability company named Forest Laboratories, LLC. On July 1, 2014, Actavis PLC ("Actavis") acquired Defendant Forest. On May 17, 2015, Actavis acquired Defendant Allergan, Inc. but maintained the name Allergan for its ongoing operations. Subsequently, on January 1, 2018, Forest Laboratories, LLC merged with and into Defendant Allergan Sales, LLC,

a Delaware limited liability company. As a result of these corporate consolidations, the Forest Defendants are predecessors in interest to Allergan Sales, LLC.

35. Defendant Allergan Sales, LLC is a Delaware limited liability company having its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

36. Defendant Allergan, Inc. is a Delaware corporation having its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

37. Defendant Allergan USA, Inc. is a Delaware corporation having its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

38. Allergan, through its merger with Forest, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making direct sales of Bystolic to Plaintiffs' assignors and other purchasers at supracompetitive prices made possible by the delay resulting from the challenged reverse payments.

39. Forest assigned the reverse-payment agreements to Allergan, and Allergan never withdrew from them.

40. Allergan joined the ongoing unlawful course of conduct and the unlawful reverse-payment agreements designed to suppress generic Bystolic competition. Allergan did not withdraw from those conspiracies and instead continued to participate in them.

41. Defendant AbbVie Inc. is a Delaware corporation having its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is the corporate successor to Allergan and Forest, having completed its purchase of Allergan on May 8, 2020.

42. Defendant AbbVie, through its merger with Allergan, assumed responsibility for

performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making direct sales of Bystolic to Plaintiffs' assignors, and other purchasers at supracompetitive prices made possible by the delay resulting from those challenged provisions.

43. Allergan assigned the reverse-payment agreements to AbbVie and AbbVie never withdrew from them.

44. AbbVie joined the ongoing unlawful course of conduct and the unlawful reverse-payment agreements designed to suppress generic Bystolic competition. AbbVie did not withdraw from those conspiracies and instead continued to participate in them.

45. Defendant Watson Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

46. Defendant Watson Laboratories, Inc. (NV) is a Nevada corporation having places of business at 132 Business Center Drive, Corona, California 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

47. Defendant Watson Laboratories, Inc. (DE) is a Delaware corporation having places of business at 311 Bonnie Circle, Corona, California 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

48. Defendant Watson Laboratories, Inc. (NY) is a New York corporation having places of business at 311 Bonnie Circle, Corona, California 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

49. Defendant Watson Laboratories, Inc. (CT) is a Connecticut corporation having places of business at 131 West St., Danbury, Connecticut, 311 Bonnie Circle, Corona, California

92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

50. Defendant Watson Pharmaceuticals, Inc. is a Nevada corporation having places of business at 311 Bonnie Circle, Corona, California 92880 and 360 Mount Kemble Avenue, Morristown, New Jersey 07962, and its corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

51. Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT) and Watson Pharma, Inc. are wholly owned subsidiaries of Watson Pharmaceuticals, Inc. and act as agents of Watson Pharmaceuticals, Inc.

52. Defendant Actavis, Inc. is a Nevada corporation having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson purchased Actavis, Inc. on October 31, 2012, and the combined company assumed the Actavis name. Both Watson and Actavis are parties to the unlawful reverse-payment agreement between Forest and Watson.

53. Defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation having its principal place of business at 5 Basel St., Petach Tikva, Israel.

54. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

55. Teva Pharmaceutical Industries Ltd. purchased Watson, then known as Actavis, on July 26, 2015. As part of the purchase, Teva agreed to adopt “all Liabilities and Claims” of Actavis. Teva Pharmaceuticals USA, Inc. is a wholly owned domestic subsidiary of Teva Pharmaceutical Industries Ltd. and is one of the largest sellers of generic drugs in the United States.



56. Defendant Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad - 380 009, Gujarat, India.

57. Defendant Torrent Pharma Inc. is a Delaware corporation having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, Michigan 49009. Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. On information and belief, Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd.

58. Defendant Amerigen Pharmaceuticals Ltd. is a Chinese company having places of business at 197 State Route 18S, Suite 306N, East Brunswick, New Jersey 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, PRC 215006.

59. Defendant Amerigen Pharmaceuticals Inc. is a Delaware corporation having a principal place of business at 197 State Route 18S, Suite 306N, East Brunswick, New Jersey 08816. Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd. and acts as the agent of Amerigen Pharmaceuticals Ltd.

60. Defendant Glenmark Generics Inc. is a Delaware corporation having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark Generics Inc. is the same entity as Glenmark Generics Inc., USA. To the extent Glenmark Generics Inc. is an entity separate and apart from Glenmark Generics Inc., USA, any allegations in this Complaint relating to Glenmark Generics Inc., USA shall apply equally to Glenmark Generics Inc.

61. Defendant Glenmark Generics Ltd. is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

62. Defendant Glenmark Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant

Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. Glenmark Generics Inc., USA and Glenmark Generics Ltd. are wholly-owned subsidiaries of Glenmark Pharmaceuticals Ltd. On information and belief, Glenmark Generics Inc., USA is the North American division of Glenmark Generics Ltd. Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. have officers and directors in common. Glenmark Generics Inc., USA acts as the agent of Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd.

63. Defendant Hetero Labs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad 500018 Andhra Pradesh, India.

64. Defendant Hetero Drugs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad 500018 Andhra Pradesh, India.

65. Defendant Hetero USA Inc. is a Delaware corporation having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd. On information and belief, Hetero USA Inc. acts as the agent of Hetero Labs Ltd.

66. Defendant Indchemie Health Specialties Private Ltd. is an Indian company having a place of business at 510, Shah & Nahar Industrial Estate, Dr. E. Moses Road, Mumbai 400018, India.

67. Defendant Alkem Laboratories Ltd. is an Indian company having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

68. Defendant Ascend Laboratories, LLC is a New Jersey limited liability company having its principal place of business at 339 Jefferson Road, Suite 101, Parsippany, NJ 07054. Ascend Laboratories, LLC is a wholly owned subsidiary of Alkem Laboratories Ltd. Ascend Laboratories, LLC is responsible for marketing, distributing and selling drugs developed by Alkem Laboratories Ltd. in the United States and is an agent of Alkem Laboratories Ltd. At the direction of Alkem Laboratories Ltd., Ascend Laboratories, LLC has agreed that it will not market the generic version of Bystolic developed by Alkem Laboratories Ltd. until September 17, 2021 when it otherwise would have done so earlier.

69. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

### **III. JURISDICTION AND VENUE**

70. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. § 15(a) & 26, and seeks to recover treble damages, permanent injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendants' antitrust violations in the United States market for nebivolol HCl. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

71. Venue is proper in this District pursuant to section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b), (c), and (d) because during the relevant period, each Defendant resided, transacted business, was found, or had agents in the United States and in this

District, and a substantial portion of the alleged conduct that affected interstate trade and commerce discussed herein has been carried out in the United States and in this District.

72. This Court has personal jurisdiction over each Defendant because each Defendant has – throughout the United States and including in this District – transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

73. This Court has personal jurisdiction over each Defendant under 15 U.S.C. § 22 because each transacts business in this District. This Court has specific personal jurisdiction under CPLR § 302(a) over all Defendants because Forest, from its then-principal place of business in New York, NY, did all of the following: (a) entered into the agreements containing the challenged reverse payments with the Generic Defendants; (b) made the promised reverse payments to its co-conspirators; (c) accepted its co-conspirators' delay of generic Bystolic in return for those reverse payments; (d) sold branded Bystolic at supracompetitive prices made possible by the generic delay purchased by those reverse payments; (e) profited from the delay of generic Bystolic competition purchased by those reverse payments; and (f) assigned to its successors (the other named defendants) its obligations and benefits from the agreements containing the challenged reverse payments. Moreover, on information and belief, some or all of the agreements containing the challenged reverse payments direct application of New York law and select a New York forum. Personal jurisdiction also lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary Defendants.

#### **IV. REGULATORY BACKGROUND**

##### **A. Characteristics of the Prescription Pharmaceutical Marketplace**

74. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person both pays for and chooses the product, the price of the product plays an appropriate role in the person's choice of products and, consequently, manufacturers have an appropriate incentive to lower the prices of their products.

75. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Bystolic, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) is obligated to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

76. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

77. The relative unimportance of price in the pharmaceutical marketplace reduces

what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

**B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs**

78. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

79. When the FDA approves a brand manufacturer’s NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the “Orange Book.” The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If any such patents issue after the FDA approves the NDA, the manufacturer must subsequently list them in the Orange Book within thirty days of their issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

80. The FDA relies completely on the brand manufacturer’s representations about patent validity and applicability, as it does not have the resources or authority to verify the

validity or applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

### **C. The Hatch-Waxman Amendments**

81. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. It must show only that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug. In other words, the ANDA must demonstrate that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

82. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

83. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic defendants, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

84. The Hatch-Waxman Amendments achieved both goals, advancing substantially

the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled \$21.6 billion; by 2009, total prescription drug revenue had increased many-fold to \$300 billion.

#### **D. Paragraph IV Certifications**

85. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
- ii. that the patent for the brand drug has expired (a "Paragraph II certification");
- iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
- iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

86. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA



may grant “tentative approval,” but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

87. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic sellers enter the market. Generics are usually at least 20% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generics on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

88. The first generic applicant can help the brand manufacturer “game the system” by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity. This tactic creates a “bottleneck” because later generic applicants cannot launch until the first generic applicant’s 180-day exclusivity has elapsed or is forfeited.

#### **E. Benefits of Generic Drugs**

89. Generic versions of brand name drugs contain the same active ingredient, and are

determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission (“FTC”) estimates that, by one year after market entry, the generic version takes over 80% of the brand’s unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as Plaintiffs, a generic typically achieves at least an 80% substitution rate within 90 days. As a result, brand name companies such as Forest, Allergan and AbbVie view competition from generic drugs as a grave threat to their bottom lines.

90. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists liberally and substantially substitute the generic version when presented with a prescription for its brand-name equivalent. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for brand prescriptions unless the prescribing physician has specifically countermanded that substitution by writing “dispense as written” or equivalent language on the prescription.

91. There is an incentive to choose the less expensive generic equivalent at every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices of generic products.

92. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost)

without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the reverse-payment agreements at issue here.

**F. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms**

93. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand name manufacturer sues the potential generic competitor for alleged patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

94. In connection with the resolution of patent litigation arising out of Paragraph IV Certifications, some brand name manufacturers have entered into "settlements" in which the brand name manufacturer pays off its generic competitors in exchange for a delay in generic competition. These exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or "reverse-payment agreements." Brand and generic manufacturers execute exclusion payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers. The brand name manufacturer preserves increased profits by keeping its monopoly intact via a payment of some of the monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.

95. Initially, reverse-payment agreements took the form of a straight cash payment

from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and lawsuits, brand name manufacturers and Generic Defendants have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. For example, the reverse-payment deals that were the subject of *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), involved payments allegedly hidden in co-promotion and manufacturing side-deals entered into in connection with settlement of patent litigation over the brand drug AndroGel. Because the profits to be gained by delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

96. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period pursuant to its own approved NDA. Such an “authorized generic” is literally identical to the brand drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both the ANDA filer’s generic drug and the authorized generic and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer’s revenues and profits.

97. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the revenues generated by the first-filer’s generic product by approximately 50% during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the

authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

98. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

99. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their brand drugs in response to the entry of AB-rated generics. Instead, they either raise the price to extract higher prices from the small number of “brand-loyal” patients or, more typically, they continue to raise the price of the brand drug at the same rate at which it was raised prior to generic entry.

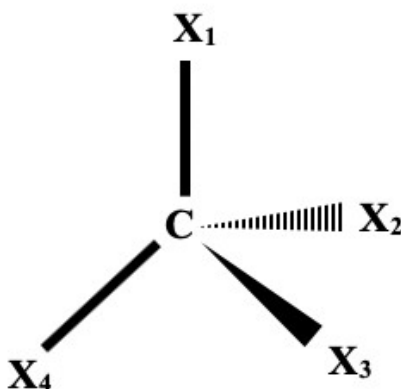
100. Given the significant negative impact of an authorized generic on the first-filing generic’s revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer’s agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market.

## **V. OPERATIVE FACTS**

### **A. Basic Chemistry Relating to the Active Pharmaceutical Ingredient in Bystolic**

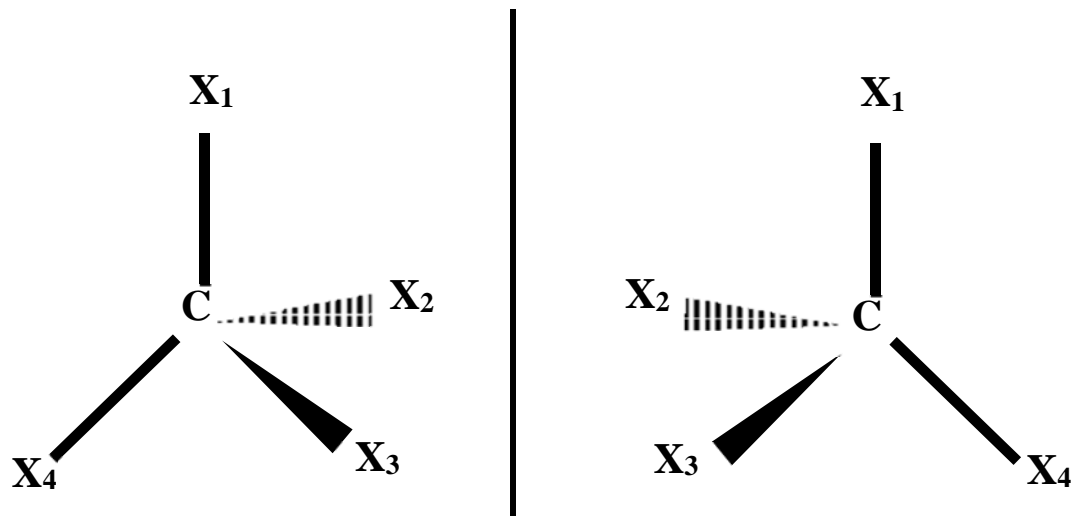
101. Molecules are composed of atoms (*e.g.*, carbon, nitrogen, or hydrogen) that are bonded to each other through the sharing of electrons. The atom carbon forms four bonds and tends to adopt a tetrahedral structure. That three-dimensional arrangement can be envisioned as a tetrahedron with the carbon atom at the center and the four substituents at the four vertices of the tetrahedron.

102. The chemical symbol for a carbon atom is “C.” The figure below depicts a carbon atom (labeled as “C”) bonded to four different chemical substituents (labeled as “X<sub>1</sub>,” “X<sub>2</sub>,” “X<sub>3</sub>,” and “X<sub>4</sub>”).



The straight lines from the carbon atom (at the center) to “X<sub>1</sub>” and “X<sub>4</sub>” are intended to convey that they are in the plane of the page. The solid wedge from the carbon atom to “X<sub>3</sub>” is intended to convey that it is coming out of the page towards the reader. And the hashed wedge from the carbon atom to “X<sub>2</sub>” is intended to convey that it is coming out of the page but away from the reader. Thus, the above figure reflects a three-dimensional tetrahedral structure with a carbon atom at its center.

103. When a carbon atom is attached to four different substituents in a tetrahedral arrangement such as that shown above, the substituents can be arranged in either of two conformations, as depicted below, with a mirror line between them. Note that, much like one’s



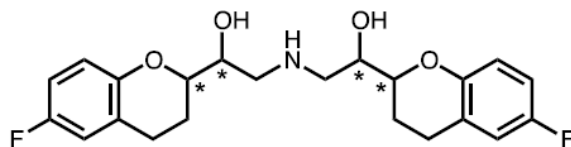
left and right hands, these two arrangements are mirror images of one another. And, much like one's left and right hands, they cannot be superimposed on one another by rotation. A carbon atom bonded to four different substituents can thus exist as either of two "stereoisomers" and such a carbon atom is referred to as a "chiral center." Naming conventions exist to distinguish these two stereoisomers from one another, and a commonly used terminology refers to one configuration as the "R" configuration and the other as the "S" configuration.

104. Distinguishing between stereoisomers can be particularly important in biological systems because many active pharmaceutical ingredients ("APIs") in drugs interact with naturally occurring receptors in the human body by fitting into a three-dimensional site on the receptor, much like a left hand fits into a left-handed glove. Just as a left hand would not fit properly into a right-handed glove, the wrong stereoisomer often will not fit into the intended receptor site. Thus, it is not uncommon for one stereoisomer to exhibit a desired pharmacological activity in biological systems while the other does not.

105. Carbon is so ubiquitous in organic chemicals that a carbon atom in chemical structures is often abbreviated as a vertex, rather than as a "C," with the understanding that such

vertices represent carbon. The chemical symbol for hydrogen is “H” and hydrogen forms only one bond. Because hydrogen is also ubiquitous and the number of chemical bonds that carbon and hydrogen make (*i.e.*, 4 and 1, respectively) is so well known, hydrogen is often omitted from chemical structures and its presence is assumed when a carbon has less than four bonded substituents.

106. On March 31, 1987, the United States Patent and Trademark Office (“PTO”) issued United States Patent No. 4,654,362 (“the ’362 Patent”). The ’362 Patent disclosed a number of different chemical compounds, including the following chemical compound:



107. The unlabeled vertices above correspond to a carbon atom, and each of those carbon atoms (vertices) is connected to other atoms. To the extent a particular carbon atom has fewer than four bonds depicted, the remainder are hydrogen atoms. With this understanding in mind, each asterisk in the above chemical structure corresponds to a chiral center – *i.e.*, a carbon atom bonded to four different substituents – that can adopt either of two configurations that can be labeled as either an “R” or “S” configuration. As a result, the above chemical structure discloses ten different possible stereoisomers with the following configurations:

1. SRRR    6. SRSS
2. RSSS    7. RSRR
3. SRRS    8. RRSS
4. RSSR    9. SSSS
5. SRSR    10. RRRR



108. Forest was, and its successor in interest Allergan is, the holder of NDA No. 21-742 for Bystolic. The active ingredient in Bystolic is a mixture of two of the above ten stereoisomers: the SRRR and RSSS stereoisomers (*i.e.*, nos. 1 and 2, above). The mixture of these two stereoisomers is referred to as nebivolol, and both are present in Bystolic as a hydrochloride salt.

#### **B. Forest's Bystolic Patents**

109. Forest certified to FDA that the '040 and '580 Patents covered Bystolic, and FDA listed those patents in the Orange Book. The '580 Patent issued on June 2, 1998 and expired seventeen years later, on June 2, 2015. Accordingly, the '580 Patent afforded Forest no protection from generic competition for Bystolic beyond June 2, 2015.

110. The '040 Patent issued from United States Application Serial No. 07/825,488 ("the '488 Application") filed on January 24, 1992. To understand the scope of the issued claims in the '040 Patent, it is important to understand the effect of the transition used in a patent claim. "A patent claim typically has three parts: the preamble, the transition, and the body." DONALD S. CHISUM, CHISUM ON PATENTS § 8.06[1](b) (2003). "The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties." *Id.* § 8.06[1](b)[i]. "The transition is a phrase connecting the preamble to the body of the claim. The content of the phrase may indicate whether the elements stated in the body are 'open' or 'closed.'" *Id.* § 8.06[1](b)[ii]. "The body of the claim is the recitation or listing of the elements and limitations which define the product or process to be encompassed within the patent monopoly." *Id.* § 8.06[1](b)[iii].

111. There are three commonly used transitional phrases: "comprising," "consisting of," and "consisting essentially of." *Id.* § 8.06[1](b)[ii]; *Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). These are "terms of art in patent law that 'define the

scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.” *Id.* (quoting the Manual of Patent Examining Procedures). At one end of the spectrum, the phrase “comprising” signifies that the claim is “open” to the addition of unrecited components or steps. *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). For example, a claim reciting a product “comprising” three ingredients A, B and C encompasses a product composed of A, B, C and D (*i.e.*, the addition of D to the A-B-C combination does not avoid infringement).

112. The originally-filed claims in the application that issued as the ’040 Patent employed the open transition “comprising.” For example, originally filed claim 19 covered pharmaceutical compositions “comprising” a “pharmaceutically acceptable carrier” and the SRRR and RSSS stereoisomers of nebivolol. The use of the open transition “comprising” meant that original claim 19 covered formulations having the SRRR and RSSS stereoisomers of nebivolol, even if the formulations also included some or all of the other eight unclaimed stereoisomers of nebivolol. The PTO examiner rejected those claims based upon the prior art ’362 Patent described above. The examiner reasoned that the ’362 Patent taught mixtures of various of the stereoisomers described above, and thus were covered by pending claim 19.

113. In response, the applicants admitted that the ’362 Patent taught “undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of the Base Compound. . . .” More specifically, the applicants admitted that “Compound 84 . . . is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 . . . is an undefined mixture of the RSRS, RSSR, and SRRS isomers.” In an attempt to overcome the rejection, the applicants narrowed the claims by substituting new claims utilizing the transition “consisting essentially of” rather than “comprising.” In doing so, the

applicants emphasized that the purpose of the amendment was to distinguish their claims from the undefined mixtures of other nebivolol isomers disclosed in the Prior Art '362 Patent:

Claims 18 and 19 have been rewritten as new Claims 25 and 26. Claim 25 recites “A composition consisting essentially of the compound . . .”, and Claim 26 recites “A pharmaceutical composition consisting essentially of . . . [the two compounds and (b)]”. This amendment is being made to more clearly distinguish the claimed invention over the prior art [’362 Patent] which, as is explained in detail below, discloses undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of [nebivolol]. Favorable consideration of the amended claims is respectfully requested.

114. The transition “consisting essentially of” in a patent claim narrows the claim relative to “comprising.” *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). “[W]ith respect to a ‘consisting essentially of’ claim, there is no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention.” *Yoon Ja Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006). Thus, for a claim reciting a product “consisting essentially of” ingredients A, B and C, the addition of unrecited ingredient D will avoid infringement if D has a material effect on the basic and novel properties of the claimed invention.

115. The PTO examiner, however, was not persuaded that the use of the “consisting essentially of” transition distinguished the then-pending claims from the ’362 Patent. He therefore maintained his rejection of the claims. The applicants for the ’040 Patent again argued that it was impossible to tell from the ’362 Patent which stereoisomers, and in what amounts, were definitely present in the disclosed mixtures:

There is no way that one can determine from the teachings of the patent the specific stereoisomeric configuration of [the prior art ’362 Patent’s] compound Nos. 84 and 87.

The Examiner continued to maintain his rejections and ultimately issued a final rejection of the “consisting essentially of” Claims 25 and 26, as anticipated by the ’362 Patent. He also rejected

the claims as obvious.

116. The applicants for the '040 Patent appealed the examiner's final anticipation and obviousness rejections to the Board of Patent Appeals and Interferences ("the Board"). In their brief, the applicants continued to argue that it was impossible to say exactly which stereoisomers (and how much of them) were present in Compound 84 of the prior art '362 Patent, but that the "possible" stereoisomers present in unknown amounts were RSRR, RSSS, SRRR and SRSS. During the course of briefing the appeal to the Board, the Examiner dropped the anticipation rejection.

117. The Board nevertheless addressed the anticipation issue and made certain findings and conclusions regarding the relationship between then-pending Claim 26 and Compound 84 of the '362 Patent. Specifically, the Board concluded:

[The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

118. The Board then determined that the "consisting essentially of" transition in then-pending Claim 26 caused the claim to cover the undefined mixture of isomers in the Prior Art '362 Patent:

It is well settled that "the phrase 'consisting essentially of' limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic(s) of a composition." Here, a basic and novel characteristic of the pharmaceutical composition of claim 26 is its blood pressure reducing or antihypertensive effect. Thus, claim 26 is open to ingredients that do not materially affect its antihypertensive activity. [The prior art '362 Patent's] antihypertensive compound 84 is a mixture of four stereoisomers: RSSS, SRRR, RSRR and SRSS. ***Because the RSSR and SRSS stereoisomers do not materially affect blood pressure reducing or antihypertensive activity, it appears that they are not excluded from the composition of claim 26.***

(internal citation omitted and emphasis added). Accordingly, the Board ordered the Examiner to

reconsider his withdrawal of the anticipation rejection based on the Prior Art '362 Patent:

Specifically, the examiner should consider whether claim 26 'reads on' [the '362 Patent's] compound 84 taking into account the appropriate principles of claim interpretation and the foregoing remarks.

The very clear upshot of the Board's decision was that the claims of the '488 Application were not patentable unless the claims excluded the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers.

119. On remand from the Board, the applicants did not even attempt to argue against anticipation in view of the Board's opinion. Instead, they further narrowed their claims by replacing "consisting essentially of" with "consisting of," in new Claims 27 and 28. And based on that change, applicants argued that the new "consisting of" limitation excluded the undefined mixture of possible stereoisomers in the '362 Patent:

Applicants respectfully submit that the claims, as amended, are patentable over [the prior art '362 Patent]. Applicants submit that neither a composition consisting of the RSSS enantiomer, nor a composition consisting of the RSSS enantiomer and its enantiomer the SRRR enantiomer, are disclosed in [the '362 Patent]. [The '362 Patent] discloses the base compound, as an undefined mixture of stereoisomers, as compound 84 (designated as "AB") and 87 (designated as "AA"), shown in the table in Col. 21 of the patent.

120. Once again, the applicants expressly noted that "Compound 84 [of the prior art '362 Patent] is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 [] is an undefined mixture of the RSRS, RSSR, and SRRS isomers." They argued that the new "consisting of" language excluded compounds containing such additional isomers:

[I]t is clear that the cited [the '362 Patent] discloses neither a composition consisting of the RSSS enantiomer of the base compound, nor a composition consisting of the RSSS and SRRR enantiomers.

121. And again, applicants did not distinguish their claims based on any particular amount or source of unrecited stereoisomers in the "undefined mixture" of the '362 Patent.

122. The phrase “consisting of” is the narrowest of the transitions, and it “signifies restriction and exclusion of unrecited steps or components.” Manual of Patent Examining Procedures § 2111.03; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). In light of the Board’s reasoning and the applicants’ comments and amendments, it is clear that the narrowing amendment was intended to and did exclude the presence of unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers (*i.e.*, the claims do not cover formulations containing the unclaimed stereoisomers, especially the RSSR and SRSS stereoisomers).

123. The Examiner allowed the “consisting of” Claims 27 and 28, which ultimately issued as Claims 2 and 3 of the ’040 Patent in 2003.

124. Subsequently, the ’040 Patent was subjected to reexamination proceedings, and a reexamination certificate issued in 2009.

### **C. The Generic Defendants File ANDAs for Generic Bystolic**

125. Alkem, Amerigen, Glenmark, Indchemie, Hetero, Torrent and Watson were the first generic manufacturers to file ANDAs with the FDA containing paragraph IV certifications regarding the Bystolic patents. In letters granting final approval to their ANDAs, the FDA noted that each was “one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets.”<sup>17</sup>

126. Because the Generic Defendants were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they shared Hatch-Waxman’s 180-day exclusivity period, *i.e.*, each Generic Defendant could sell generic Bystolic during the 180-day

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<sup>17</sup> See, e.g., 11/27/2015 Letter from FDA to Watson, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203683Orig1s000Ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf); 5/27/2017 Letter from FDA to Glenmark, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2017/203821Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf); 6/24/2015 Letter from FDA to Alkem, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203741Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf).

exclusivity period when the FDA would not finally approve any later-filed ANDA for generic Bystolic.

127. Forest received the Generic Defendants' Paragraph IV notice letters on the following dates:

- Torrent: February 2, 2012<sup>18</sup>
- Indchemie: February 3, 2012<sup>19</sup>
- Alkem: February 3, 2012<sup>20</sup>
- Watson: February 13, 2012<sup>21</sup>
- Amerigen: February 16, 2012<sup>22</sup>
- Glenmark: February 20, 2012<sup>23</sup>
- Hetero: February 17, 2012<sup>24</sup>

128. Because they contained Paragraph IV certifications, these notice letters were required to include a detailed statement of the factual and legal bases as to why the '040 Patent was invalid, unenforceable, and/or not infringed by their ANDA products. The Paragraph IV notice letters were required to include an offer of confidential access to each Generic

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<sup>18</sup> *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 93).

<sup>19</sup> *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1 ¶ 22).

<sup>20</sup> *Id.* ¶ 38.

<sup>21</sup> *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 108).

<sup>22</sup> *Id.* ¶ 123.

<sup>23</sup> *Id.* ¶ 138.

<sup>24</sup> *Id.* ¶ 153.

Defendant's ANDA under the Hatch-Waxman Act. The notice letters gave rise to a potential cause of action for patent infringement, thereby allowing Forest to file suit against the Generic Defendants under the Hatch-Waxman Act (assuming that Forest had a basis to sue under Rule 11 of the Federal Rules of Civil Procedure).

#### **D. The Bystolic Patent Litigation**

129. On March 13, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Torrent, Watson, Amerigen, Glenmark, and Hetero.<sup>25</sup>

130. On March 14, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the Northern District of Illinois against Indchemie and Alkem.<sup>26</sup>

131. By order of the Judicial Panel for Multidistrict Litigation, these cases were consolidated into *In re Nebivolol Patent ('040) Litigation*, 12-cv-5026 (N.D. Ill. June 12, 2012) (ECF No. 1) (hereafter referred to as the "Nebivolol Patent Litigation").

132. Forest could not prevail in the Nebivolol Patent Litigation. The sole independent claim asserted by Forest in the Bystolic Patent Litigation was claim 2, as shown below:

2. A pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients:

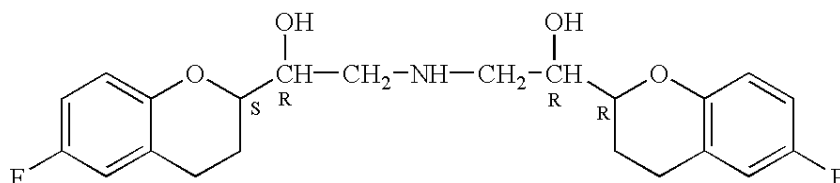
(a) the blood pressure reducing compound [2S,αR, 2'R,α'R]-α,α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:

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<sup>25</sup> *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1).

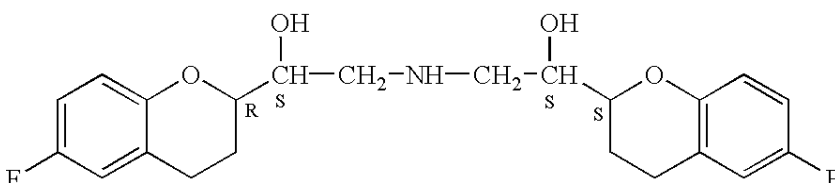
<sup>26</sup> *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1).





or a pharmaceutically acceptable acid addition salt thereof; and

(b) the compound [2R,αS,2'S,α'S]-α,α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof.

'040 Patent at 11:33-12:22. Thus, claim 2 is limited to a pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients, SRRR-nebivolol and RSSS-nebivolol (or pharmaceutically acceptable acid addition salts).

133. The Generic Defendants were well aware of the prosecution history of the '040 Patent and the narrowing amendments the applicants had made during prosecution. During claim construction proceedings in the Nebivolol Patent Litigation, the Generic Defendants correctly argued that the term “consisting of” in claim 2 of the '040 Patent “excludes any unrecited stereoisomers of nebivolol.” The Generic Defendants’ products did not infringe because they included at least small amounts of the unrecited stereoisomers of nebivolol, including the RSSR and SRSS stereoisomers.

134. Early on in the Bystolic Patent Litigation, the Generic Defendants pressed the argument that the “consisting of” transition precluded the use of a plurality of inactive ingredients. Their position was premised on the argument that (1) a “pharmaceutically acceptable

carrier” referred to an individual inactive ingredient in a pharmaceutical formulation; (2) the “consisting of” transition “closed” the claim to unrecited inactive ingredients; and (3) therefore, the claims did not cover formulations having two or more inactive ingredients. At least one other court has construed “pharmaceutically acceptable carrier” to mean “a conventional pharmaceutically acceptable excipient or additive. . . .” *Schering Corp. v. Mylan Pharms., Inc.*, 2011 U.S. Dist. LEXIS 63825, at \*36 (D.N.J. Jun. 15, 2011). To the extent this interpretation applied in the Nebivolol Patent Litigation, the Generics’ products did not infringe for this additional reason.

135. As a result of the foregoing, Forest could not prevail in proving literal infringement of the asserted claims of the ’040 Patent. And, in light of the prosecution history of the ’040 Patent, Forest could not prevail based on the doctrine of equivalents. In addition, Forest’s validity contentions concerning the asserted claims of the ’040 Patent were weak, and it could not have prevailed against the Generics’ invalidity arguments. As the Board explained during the prosecution of the ’040 Patent:

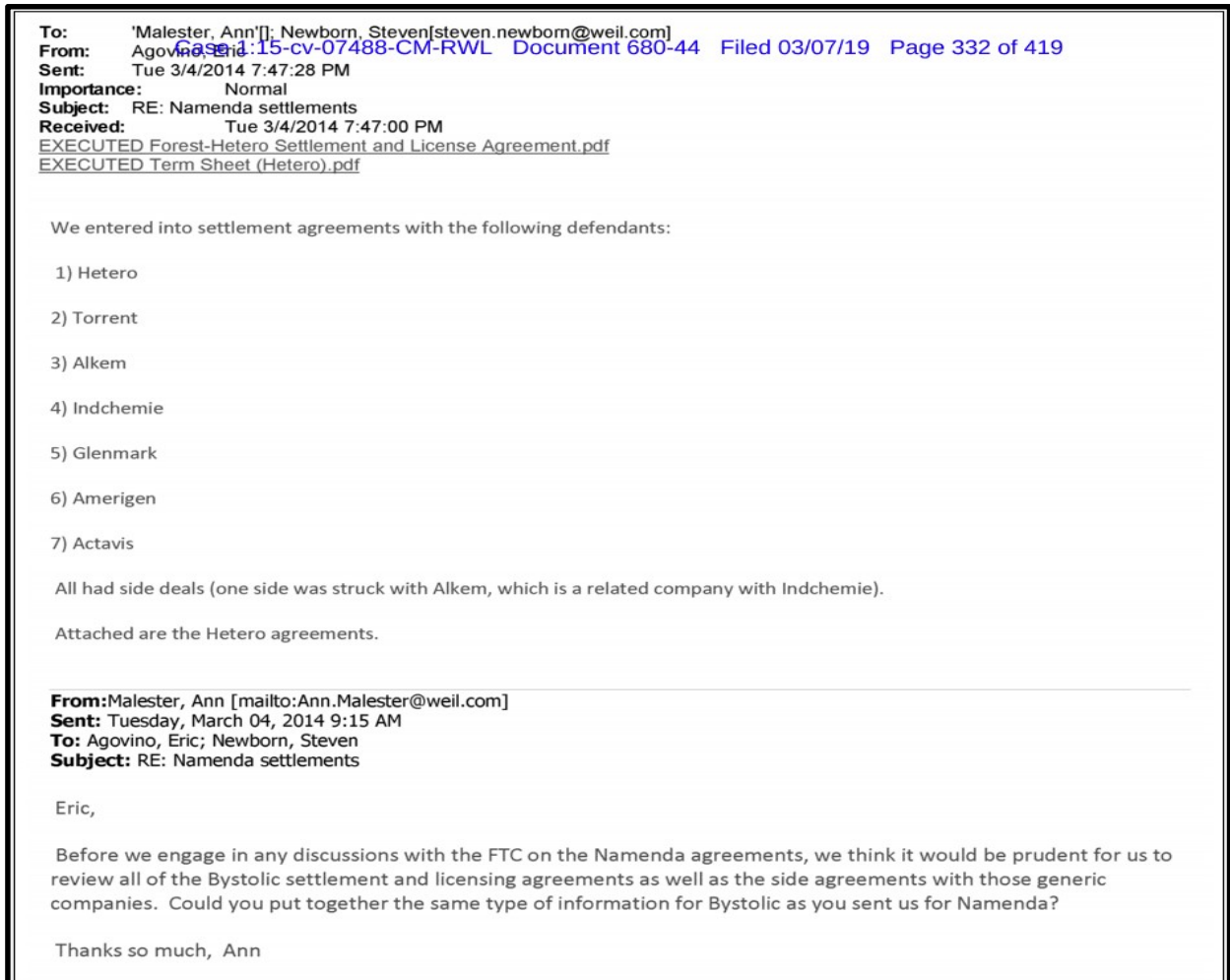
[The ’362 Patent’s] disclosure of compound 84, together with its designation “AB,” appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers “just as surely as if they were identified in the reference by name.”

The ’362 Patent was prior art to the ’040 Patent. In light of the ’362 Patent’s essentially explicit teaching of a mixture of “the individual RSSS, SRRR, RSRR and SRSS stereoisomers” of nebivolol, the asserted compositions in the ’040 Patent were anticipated by, or obvious in view of, the prior art, including other pertinent prior art such as Van de Water et al., *Pharmacological and Hemodynamic Profile of Nebivolol, a Chemically Novel, Potent, and Selective B1- Adrenergic Antagonist*, JOURNAL OF CARDIOVASCULAR PHARMACOLOGY, 11, No. 5, 552-563 (1988). Any purported evidence of secondary indicia of nonobviousness was insufficient to overcome the clear

prima facie obviousness of the claims.

### E. Forest's Unlawful Reverse-Payment Agreements with the Generic Defendants

136. Starting on October 24, 2012, Forest began entering into settlements with each of the Generic Defendants to resolve the Nebivolol Patent Litigation. Forest's internal and external counsel have conceded that each of these settlements also included "side-deals":



137. These side-deals were also listed in Forest's Merger Agreement with Actavis, as "material contracts" that on information and belief "involve payments . . . of consideration in

excess of \$15,000,000.”<sup>27</sup> In addition, Forest also has admitted that it reimbursed “certain of the Settling Defendants’ legal costs in connection with the patent litigation.”<sup>28</sup> Accordingly, on information and belief, Forest paid each Generic Defendant at least \$15,000,000, but likely more, in reverse payments to resolve the Nebivolol Patent Litigation and induce the Generic Defendants to quit the patent fight.

138. The **Hetero** reverse payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012,” plus payment for Hetero’s expended litigation costs, and a “FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>29</sup>

139. On information and belief, in addition to the monies Forest paid Hetero for Hetero’s expended litigation costs, pursuant to the “FINAL TERM SHEET,” Forest paid Hetero more than \$15,000,000.

140. The **Torrent** reverse payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012,” plus payment for Torrent’s expended litigation costs, and a “PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd. and Forest Laboratories Holdings Ltd. dated November 21, 2012, in

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<sup>27</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

<sup>28</sup> <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>.

<sup>29</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 179).

connection with the settlement of BYSTOLIC patent dispute.”<sup>30</sup>

141. On information and belief, in addition to the monies Forest paid Torrent for Torrent’s expended litigation costs, pursuant to the “PATENT ASSIGNMENT AGREEMENT,” Forest paid Torrent more than \$15,000,000.

142. The **Alkem** reverse payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012,” plus payment for Alkem’s expended litigation costs, and a “TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute.” Alkem and Forest also entered into an “AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT . . . on January 9, 2013.”<sup>31</sup>

143. On information and belief, in addition to the monies Forest paid Alkem for Alkem’s expended litigation costs, pursuant to the Alkem “TERM SHEET,” Forest paid Alkem more than \$15,000,000.

144. The **Indchemie** reverse payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012,” plus payment for Indchemie’s expended litigation costs, and a “TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>32</sup>

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<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

145. On information and belief, in addition to the monies Forest paid Indchemie for Indchemie's expended litigation costs, pursuant to the Indchemie "TERM SHEET," Forest paid Indchemie more than \$15,000,000.

146. The **Glenmark** reverse payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012," plus payment for Glenmark's expended litigation costs, and a "COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."<sup>33</sup>

147. On information and belief, in addition to the monies Forest paid Glenmark for Glenmark's expended litigation costs, pursuant to the "COLLABORATION AND OPTION AGREEMENT," Forest paid Glenmark more than \$15,000,000.

148. The **Amerigen** reverse payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013," plus payment for Amerigen's expended litigation costs, and a "BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."<sup>34</sup>

149. On information and belief, in addition to the monies Forest paid Amerigen for Amerigen's expended litigation costs, pursuant to the "BINDING TERM SHEET COLLABORATION AGREEMENT," Forest paid Amerigen more than \$15,000,000.

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<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at 180.

150. The **Watson** reverse payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013,” plus payment for **Watson** expended litigation costs, and “(a) the LETTER from Forest Laboratories, Inc. to Moshka8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute.”<sup>35</sup>

151. On information and belief, in addition to the monies Forest paid Watson for Watson’s expended litigation costs, pursuant to the “(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc.,” Forest paid Watson more than \$15,000,000.

152. On information and belief, the value of each reverse payment exceeded Forest’s avoided litigation costs.

153. In exchange for these reverse payments, each Generic Defendant agreed not to compete with Forest in the market for nebivolol HCl, in which Forest had a monopoly, until September 17, 2021 (a mere three months prior to expiry of the ’040 Patent) so long as all others did so as well.<sup>36</sup>

154. The purpose and effect of the reverse-payment agreements were to delay Forest from having to face lower-priced generic competition for years.

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<sup>35</sup> *Id.*

<sup>36</sup> <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>.

155. But for the reverse-payment agreements, the Generic Defendants would have been ready, able, and willing to launch generic Bystolic much earlier.

156. Specifically, the Generic Defendants would have launched by the later of: (a) June 2015, which was the expiration of the only other patent that Forest contended covered Bystolic (the '580 Patent), or (b) the date their ANDAs were finally approved.<sup>37</sup>

157. By operation of the CLPs, if *just one* Generic Defendant had launched a generic version of Bystolic prior to September 17, 2021, *all* of the other Generic Defendants would have entered the market.

158. By about October 2012, when Forest and the Generic Defendants began entering into the reverse-payment agreements, Bystolic was generating hundreds of millions of dollars per year in revenues for Forest. The loss of a substantial portion of that revenue stream had any of the Generic Defendants prevailed on non-infringement or other defenses would have drastically reduced Forest's profits. Thus, Forest had enormous incentives to avoid competition from the Generic Defendants by entering into the challenged reverse-payment agreements.

159. Forest's willingness to provide large payments to each Generic Defendant in exchange for a multi-year delay in competition amounted to an agreement to share with the Generic Defendants the monopoly profits from sales of branded Bystolic at supracompetitive levels.

## VI. ANTICOMPETITIVE EFFECTS

160. The reverse payments enabled Defendants to: (a) avoid the risk of competition from the Brand Defendants' patent being found invalid or not infringed and less-expensive

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<sup>37</sup> See ¶ 6, *supra*.



generic Bystolic coming to market in the United States prior to September 17, 2021; (b) fix, raise, maintain, or stabilize the price of Bystolic products; and (c) allocate to the Brand Defendants 100% of the U.S. market for Bystolic and its generic equivalents until September 17, 2021.

161. But for the unlawful reverse-payment agreements, reasonable companies in the position of the Generic Defendants would have begun selling a less expensive generic version of Bystolic much earlier than September 17, 2021. Such sales would have hypothetically occurred via market entry by any of the Generic Defendants upon a litigation victory by one or more Generic Defendants, at risk (that is, while the patent litigation remained pending), or via a licensed entry in a settlement with Forest that did not include a side-deal or any other unlawful reverse payments from Forest to any Generic Defendant.

162. An increasingly competitive market for Bystolic and its generic equivalents, with lower prices, would have thereafter emerged as additional generic versions of Bystolic (including an authorized generic version of Bystolic) entered the market. Plaintiffs and their assignors would have purchased generic Bystolic as soon as it became available.

163. Defendants' unlawful concerted action has (a) delayed and suppressed the sale of generic Bystolic in the United States, (b) enabled Defendants to sell Bystolic at artificially inflated, supracompetitive prices, and (c) caused Plaintiffs and their assignors to pay supracompetitive prices for nebivolol HCl tablets.

164. Thus, Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

## **VII. ANTITRUST IMPACT**

165. During the relevant period, Plaintiffs' assignors purchased substantial amounts of nebivolol HCl directly from Forest and its successors at supracompetitive prices. As a result of

Defendants' illegal conduct, Plaintiffs and their assignors were compelled to pay and did pay artificially inflated prices for their requirements of nebivolol HCl. Those prices were substantially greater than the prices that Plaintiffs and their assignors would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs and their assignors were deprived of the opportunity to purchase lower-priced generic Bystolic instead of higher-priced brand Bystolic, and (2) Plaintiffs and their assignors will pay higher prices for generic Bystolic when it becomes available than they would have paid if generic Bystolic had become available years ago.

166. As a consequence, Plaintiffs have sustained and will continue to sustain substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

167. Defendants' conspiracy continues to the present day, and Plaintiffs' injuries are ongoing. As a result of Defendants' unlawful conduct, generic Bystolic will remain unavailable until September 17, 2021 and will be more expensive when it becomes available than it would have been absent Defendants' unlawful conduct. Plaintiffs (and their assignors) will continue to pay supracompetitive prices for nebivolol HCl for months or (more likely) years after September 17, 2021. Thus, Defendants' conduct threatens continuing loss and damage to Plaintiffs unless enjoined by this Court.

#### **VIII. INTERSTATE COMMERCE**

168. The drugs at issue in this case are manufactured and sold in interstate commerce, and Defendants' unlawful conduct alleged herein has occurred in, and has had a substantial effect on, interstate commerce.

#### **IX. MONOPOLY POWER AND MARKET DEFINITION**

169. At all relevant times, the Brand Defendants had monopoly power with respect to

nebivolol HCl products because they had the power to maintain the price of the drug they sold as Bystolic at supracompetitive levels without losing sales to other products that would have made the supracompetitive prices unprofitable.

170. A small but significant, non-transitory price increase for Bystolic would not have caused a significant loss of sales to non-nebivolol HCl products.

171. Bystolic does not exhibit the significant, positive cross-elasticity of demand with any pharmaceutical product for treatment of high blood pressure that it would have with respect to AB-rated generic Bystolic. Indeed, the Brand Defendants never lowered the price of Bystolic in response to the pricing of any non-nebivolol HCl treatments for high blood pressure. In fact, the Brand Defendants substantially increased the price of Bystolic – by more than 60% – over the last five years.

172. Bystolic is differentiated from all other treatments for high blood pressure, but would not be differentiated in any substantial respect from AB-rated generic Bystolic.

173. The Brand Defendants needed to control only nebivolol HCl, and no other products, in order to maintain the price of Bystolic profitably at supracompetitive prices. No non-nebivolol HCl product ever rendered the Brand Defendants unable to profitably maintain or raise their prices of Bystolic without losing substantial sales. Only the introduction of AB-rated generic Bystolic will eliminate Brand Defendants' ability to maintain supracompetitive prices for Bystolic without losing substantial sales.

174. The Brand Defendants also sold Bystolic at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

175. The Brand Defendants have had, and exercised, the power to exclude and restrict competition to nebivolol HCl.

176. The Brand Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

177. There is direct evidence sufficient to show the Brand Defendants' monopoly power without the need to engage in market definition and calculate market shares. That evidence includes, among other things, the large reverse payments to potential generic manufacturers of generic Bystolic, which constitute "a strong indicator" of "the power to charge prices higher than the competitive level."<sup>38</sup> A firm that lacks monopoly power is not "likely to pay 'large sums' to induce 'others to stay out of its market.'"<sup>39</sup> In addition, the Brand Defendants earned extremely high monopoly profits on Bystolic that they would not have earned in a competitive market. However, to the extent that proof of monopoly power by defining a relevant product market is required, the relevant antitrust product market is the market for Bystolic and its AB-rated generic equivalents (when available), and the relevant geographic market is the United States.

178. At all relevant times, the Brand Defendants' market share in the relevant market has been and remains 100%, implying a substantial amount of monopoly power.

## **X. CLAIM ONE**

### **VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT BETWEEN BRAND DEFENDANTS AND HETERO)**

179. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Hetero.

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<sup>38</sup> *Actavis*, 570 U.S. at 157 (citation omitted).

<sup>39</sup> *Id.*

180. Defendants Forest, Allergan, AbbVie and Hetero have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of section 1 of the Sherman Act, 15 U.S.C. § 1.

181. On or about October 5, 2012, Forest, Allergan, AbbVie and Hetero entered into an illegal contract, combination or conspiracy in restraint of trade under which the Brand Defendants agreed to make large reverse payments to Hetero in exchange for Hetero's agreement to delay bringing generic Bystolic to the market until September 17, 2021. This agreement and its effects continue to the present day. The purpose and effect of this reverse-payment agreement were to: (a) allocate to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

182. The Hetero reverse payments were large and unjustified.

183. The Hetero reverse-payment agreement harmed Plaintiffs as set forth above.

184. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments to Hetero that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

185. As a direct, proximate, foreseeable, and intended result of the Hetero reverse-payment agreement in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages. Specifically, without a reverse payment, Hetero would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Hetero would have agreed to

an entry date not delayed by the unlawful Hetero reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Hetero and Forest would also have applied to any earlier-settling Generic Defendant.

## **XI. CLAIM TWO**

### **VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT BETWEEN BRAND DEFENDANTS AND TORRENT)**

186. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Forest, Allergan, AbbVie and Torrent.

187. Forest, Allergan, AbbVie and Torrent have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

188. On or about November 21, 2012, Forest, Allergan, AbbVie and Torrent entered into an illegal contract, combination or conspiracy in restraint of trade under which the Brand Defendants agreed to make large reverse payments to Torrent in exchange for Torrent's agreement to delay bringing generic Bystolic to the market until September 17, 2021. This agreement and its effects continue to the present day. The purpose and effect of this reverse-payment agreement were to: (a) allocate to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

189. The Torrent reverse payments were large and unjustified.

190. The Torrent reverse-payment agreement harmed Plaintiffs as set forth above.

191. There is and was no legitimate, non-pretextual, procompetitive justification for the

reverse payments to Torrent that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

192. As a direct, proximate, foreseeable, and intended result of the Torrent reverse-payment agreement in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages. Specifically, without a reverse payment, Torrent would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Torrent would have agreed to an entry date not delayed by the unlawful Torrent reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Torrent and Forest would also have applied to any earlier-settling Generic Defendant.

## **XII. CLAIM THREE**

### **VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT BETWEEN BRAND DEFENDANTS AND ALKEM)**

193. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Forest, Allergan, AbbVie and Alkem.

194. Forest, Allergan, AbbVie and Alkem have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

195. On or about November 27, 2012, Forest, Allergan, AbbVie and Alkem entered into an illegal contract, combination or conspiracy in restraint of trade under which the Brand Defendants agreed to make large reverse payments to Alkem in exchange for Alkem's agreement to delay bringing generic Bystolic to the market until September 17, 2021. This agreement and its effects continue to the present day. The purpose and effect of this reverse-payment agreement was

to: (a) allocate to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

196. The Alkem reverse payments were large and unjustified.

197. The Alkem reverse-payment agreement harmed Plaintiffs as set forth above.

198. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments to Alkem that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

199. As a direct, proximate, foreseeable, and intended result of the Alkem reverse-payment agreement in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages. Specifically, without a reverse payment, Alkem would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Alkem would have agreed to an entry date not delayed by the unlawful Alkem reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Alkem and Forest would also have applied to any earlier-settling Generic Defendant.

### **XIII. CLAIM FOUR**

#### **VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT BETWEEN BRAND DEFENDANTS AND INDICHEMIE)**

200. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Indchemie.



201. Forest, Allergan, AbbVie and Indchemie have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

202. On or about November 27, 2012, Forest, Allergan, AbbVie and Indchemie entered into and maintained an illegal contract, combination or conspiracy in restraint of trade under which the Brand Defendants agreed to make large reverse payments to Indchemie in exchange for Indchemie's agreement to delay bringing generic Bystolic to the market until September 17, 2021. This agreement and its effects continue to the present day. The purpose and effect of this reverse-payment agreement were to: (a) allocate to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

203. The Indchemie reverse payments were large and unjustified.

204. The Indchemie reverse-payment agreement harmed Plaintiffs as set forth above.

205. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments to Indchemie that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

206. As a direct, proximate, foreseeable, and intended result of the Indchemie reverse-payment agreement in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages. Specifically, without a reverse payment, Indchemie would have launched its generic version of Bystolic at risk upon receiving final FDA approval, or after a litigation

victory, or via a settlement agreement pursuant to which the Brand Defendants and Indchemie would have agreed to an entry date not delayed by the unlawful Indchemie reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Indchemie and Forest would also have applied to any earlier-settling Generic Defendant.

#### **XIV. CLAIM FIVE**

##### **VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT BETWEEN BRAND DEFENDANTS AND GLENMARK)**

207. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Glenmark.

208. Forest, Allergan, AbbVie and Glenmark have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

209. On or about December 21, 2012, Forest, Allergan, AbbVie and Glenmark entered into an illegal contract, combination or conspiracy in restraint of trade under which the Brand Defendants agreed to make large reverse payments to Glenmark in exchange for Glenmark's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The agreement and its effects continue to the present day. The purpose and effect of this reverse-payment agreement were to: (a) allocate to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

210. The Glenmark reverse payments were large and unjustified.

211. The Glenmark reverse-payment agreement harmed Plaintiffs as set forth above.

212. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments to Glenmark that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

213. As a direct, proximate, foreseeable, and intended result of the Glenmark reverse-payment agreement in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages. Specifically, without a reverse payment, Glenmark would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Glenmark would have agreed to an entry date not delayed by the unlawful Glenmark reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Glenmark and Forest would also have applied to any earlier-settling Generic Defendant.

## **XV. CLAIM SIX**

### **VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT BETWEEN BRAND DEFENDANTS AND AMERIGEN)**

214. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Amerigen.

215. Forest, Allergan, AbbVie and Amerigen have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

216. On or about July 18, 2013, Forest, Allergan, AbbVie and Amerigen entered into an illegal contract, combination or conspiracy in restraint of trade under which the Brand

Defendants agreed to make large reverse payments to Amerigen in exchange for Amerigen's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The agreement and its effects continue to the present day. The purpose and effect of this reverse-payment agreement were to: (a) allocate to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

217. The Amerigen reverse payments were large and unjustified.

218. The Amerigen reverse-payment agreement harmed Plaintiffs as set forth above.

219. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments to Amerigen that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

220. As a direct, proximate, foreseeable, and intended result of the Amerigen reverse-payment agreement in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages. Specifically, without a reverse payment, Amerigen would have launched its generic version of Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Amerigen would have agreed to an entry date not delayed by the unlawful Amerigen reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Amerigen and Forest would also have applied to any earlier-settling Generic Defendant.

**XVI. CLAIM SEVEN**

**VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1  
(AGREEMENT BETWEEN BRAND DEFENDANTS AND WATSON)**

221. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Watson.

222. Forest, Allergan, AbbVie and Watson have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

223. On or about November 1, 2013, Forest, Allergan, AbbVie and Watson entered into and maintained an illegal contract, combination or conspiracy in restraint of trade under which the Brand Defendants agreed to make large reverse payments to Watson in exchange for Watson's agreement to delay bringing generic Bystolic to the market until September 17, 2021. This agreement and its effects continue to the present day. The purpose and effect of this reverse-payment agreement were to: (a) allocate to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

224. The Watson reverse payments were large and unjustified.

225. The Watson reverse-payment agreement harmed Plaintiffs as set forth above.

226. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments to Watson that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least

restrictive means of achieving, such a purpose.

227. As a direct, proximate, foreseeable, and intended result of the Watson reverse-payment agreement in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages. Specifically, without a reverse payment, Watson would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Watson would have agreed to an entry date not delayed by the unlawful Watson reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Watson and Forest would also have applied to any earlier-settling Generic Defendant.

## **XVII. CLAIM EIGHT**

### **VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE BETWEEN BRAND DEFENDANTS AND HETERO)**

228. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Hetero.

229. At all relevant times prior to September 17, 2021, the Brand Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. The Brand Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

230. Through the Hetero reverse-payment agreement, Forest, Allergan, AbbVie and Hetero conspired to unlawfully maintain the Brand Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic Bystolic.

231. The Hetero reverse-payment agreement (a) allocated to the Brand Defendants

100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

232. The goal, purpose and/or effect of the Hetero reverse-payment agreement was to maintain, enhance, and extend the Brand Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Hetero reverse-payment agreement was intended to and did prevent and/or delay generic competition to Bystolic and enabled the Brand Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

233. Forest, Allergan, AbbVie and Hetero knowingly and intentionally conspired to maintain, enhance, and extend the Brand Defendants' monopoly power in the relevant market.

234. Forest, Allergan, AbbVie and Hetero specifically intended that the reverse-payment agreement would maintain the Brand Defendants' monopoly power in the relevant market, and injure Plaintiffs thereby.

235. Forest, Allergan, AbbVie and Hetero each committed at least one overt act in furtherance of the conspiracy.

236. As a direct, proximate, foreseeable, and intended result of Forest's, Allergan's, AbbVie's and Hetero's concerted monopolistic conduct, as alleged herein, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power and Plaintiffs were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Hetero would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Hetero would have agreed to an entry date not delayed by the unlawful Hetero

reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Forest and Hetero would also have applied to any earlier-settling Generic Defendant.

### **XVIII. CLAIM NINE**

#### **VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE BETWEEN BRAND DEFENDANTS AND TORRENT)**

237. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Torrent.

238. At all relevant times prior to September 17, 2021, the Brand Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. The Brand Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

239. Through the Torrent reverse-payment agreement, Forest, Allergan, AbbVie and Torrent conspired to unlawfully maintain the Brand Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic Bystolic.

240. The Torrent reverse-payment agreement (a) allocated to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

241. The goal, purpose and/or effect of the Torrent reverse-payment agreement was to maintain, enhance, and extend the Brand Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Torrent reverse-payment agreement was intended to and



did prevent and/or delay generic competition to Bystolic and enabled the Brand Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

242. Forest, Allergan, AbbVie and Torrent knowingly and intentionally conspired to maintain, enhance, and extend the Brand Defendants' monopoly power in the relevant market.

243. Forest, Allergan, AbbVie and Torrent specifically intended that the reverse-payment agreement would maintain the Brand Defendants' monopoly power in the relevant market, and injure Plaintiffs thereby.

244. Forest, Allergan, AbbVie and Torrent each committed at least one overt act in furtherance of the conspiracy.

245. As a direct, proximate, foreseeable, and intended result of Forest's, Allergan's, AbbVie's and Torrent's concerted monopolistic conduct, as alleged herein, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power and Plaintiffs were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Torrent would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Torrent would have agreed to an entry date not delayed by the unlawful Torrent reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Forest and Torrent would also have applied to any earlier-settling Generic Defendant.

#### **XIX. CLAIM TEN**

##### **VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE BETWEEN BRAND DEFENDANTS AND ALKEM)**

246. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Alkem.

247. At all relevant times prior to September 17, 2021, the Brand Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. The Brand Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

248. Through the Alkem reverse-payment agreement, Forest, Allergan, AbbVie and Alkem conspired to unlawfully maintain the Brand Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic Bystolic.

249. The Alkem reverse-payment agreements (a) allocated to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

250. The goal, purpose and/or effect of the Alkem reverse-payment agreements was to maintain, enhance, and extend the Brand Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Alkem reverse-payment agreement was intended to and did prevent and/or delay generic competition to Bystolic and enabled the Brand Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

251. Forest, Allergan, AbbVie and Alkem knowingly and intentionally conspired to maintain, enhance, and extend the Brand Defendants' monopoly power in the relevant market.

252. Forest, Allergan, AbbVie and Alkem specifically intended that the reverse-payment agreement would maintain the Brand Defendants' monopoly power in the relevant market, and injure Plaintiffs thereby.

253. Forest, Allergan, AbbVie and Alkem each committed at least one overt act in furtherance of the conspiracy.

254. As a direct, proximate, foreseeable, and intended result of Forest's, Allergan's, AbbVie's and Alkem's concerted monopolistic conduct, as alleged herein, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power and Plaintiffs were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Alkem would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Alkem would have agreed to an entry date not delayed by the unlawful Alkem reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Forest and Alkem would also have applied to any earlier-settling Generic Defendant.

## **XX. CLAIM ELEVEN**

### **VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE BETWEEN BRAND DEFENDANTS AND INDICHEMIE)**

255. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Indchemie.

256. At all relevant times prior to September 17, 2021, the Brand Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. The Brand Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

257. Through the Indchemie reverse-payment agreement, Forest, Allergan, AbbVie and Indchemie conspired to unlawfully maintain the Brand Defendants' monopoly power in the

relevant market by agreeing to block and delay market entry of generic Bystolic.

258. The Indchemie reverse-payment agreement (a) allocated to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

259. The goal, purpose and/or effect of the Indchemie reverse-payment agreement was to maintain, enhance, and extend the Brand Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Indchemie reverse-payment agreement was intended to and did prevent and/or delay generic competition to Bystolic and enabled the Brand Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

260. Forest, Allergan, AbbVie and Indchemie knowingly and intentionally conspired to maintain, enhance, and extend the Brand Defendants' monopoly power in the relevant market.

261. Forest, Allergan, AbbVie and Indchemie specifically intended that the reverse-payment agreement would maintain the Brand Defendants' monopoly power in the relevant market, and injure Plaintiffs thereby.

262. Forest, Allergan, AbbVie and Indchemie each committed at least one overt act in furtherance of the conspiracy.

263. As a direct, proximate, foreseeable, and intended result of Forest's, Allergan's, AbbVie's and Indchemie's concerted monopolistic conduct, as alleged herein, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power and Plaintiffs were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Indchemie would have launched generic Bystolic at risk upon receiving final

FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Indchemie would have agreed to an entry date not delayed by the unlawful Indchemie reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Forest and Indchemie would also have applied to any earlier-settling Generic Defendant.

## **XXI. CLAIM TWELVE**

### **VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE BETWEEN BRAND DEFENDANTS AND GLENMARK)**

264. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Glenmark.

265. At all relevant times prior to September 17, 2021, the Brand Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. The Brand Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

266. Through the Glenmark reverse-payment agreement, Forest, Allergan, AbbVie and Glenmark conspired to unlawfully maintain the Brand Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic Bystolic.

267. The Glenmark reverse-payment agreement (a) allocated to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

268. The goal, purpose and/or effect of the Glenmark reverse-payment agreement was to maintain, enhance, and extend the Brand Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Glenmark reverse-payment agreement was intended to and did prevent and/or delay generic competition to Bystolic and enabled the Brand Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

269. Forest, Allergan, AbbVie and Glenmark knowingly and intentionally conspired to maintain, enhance, and extend the Brand Defendants' monopoly power in the relevant market.

270. Forest, Allergan, AbbVie and Glenmark specifically intended that the reverse-payment agreement would maintain the Brand Defendants' monopoly power in the relevant market, and injure Plaintiffs thereby.

271. Forest, Allergan, AbbVie and Glenmark each committed at least one overt act in furtherance of the conspiracy.

272. As a direct, proximate, foreseeable, and intended result of Forest's, Allergan's, AbbVie's and Glenmark's concerted monopolistic conduct, as alleged herein, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power and Plaintiffs were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Glenmark would have launched generic Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Glenmark would have agreed to an entry date not delayed by the unlawful Glenmark reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Forest and Glenmark would also have applied to any earlier-settling Generic Defendant.

**XXII. CLAIM THIRTEEN**

**VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2  
(CONSPIRACY TO MONOPOLIZE BETWEEN  
BRAND DEFENDANTS AND AMERIGEN)**

273. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan, AbbVie and Amerigen.

274. At all relevant times prior to September 17, 2021, the Brand Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. The Brand Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

275. Through the Amerigen reverse-payment agreement, Forest, Allergan, AbbVie and Amerigen conspired to unlawfully maintain the Brand Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic Bystolic.

276. The Amerigen reverse-payment agreement (a) allocated to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

277. The goal, purpose and/or effect of the Amerigen reverse-payment agreements was to maintain, enhance, and extend the Brand Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Amerigen reverse-payment agreement was intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

278. Forest, Allergan, AbbVie and Amerigen knowingly and intentionally conspired to maintain, enhance, and extend the Brand Defendants' monopoly power in the relevant market.

279. Forest, Allergan, AbbVie and Amerigen specifically intended that the reverse-payment agreement would maintain the Brand Defendants' monopoly power in the relevant market, and injure Plaintiffs thereby.

280. Forest, Allergan, AbbVie and Amerigen each committed at least one overt act in furtherance of the conspiracy.

281. As a direct, proximate, foreseeable, and intended result of Forest's, Allergan's, AbbVie's and Amerigen's concerted monopolistic conduct, as alleged herein, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power and Plaintiffs were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Amerigen would have launched its generic version of Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Amerigen would have agreed to an entry date not delayed by the unlawful Amerigen reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Forest and Amerigen would also have applied to any earlier-settling Generic Defendant.

### **XXIII. CLAIM FOURTEEN**

#### **VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE BETWEEN BRAND DEFENDANTS AND WATSON)**

282. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Forest, Allergan, AbbVie and Watson.

283. At all relevant times prior to September 17, 2021, the Brand Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant



market. The Brand Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

284. Through the Watson reverse-payment agreement, Forest, Allergan, AbbVie and Watson conspired to unlawfully maintain the Brand Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic Bystolic.

285. The Watson reverse-payment agreement (a) allocated to the Brand Defendants 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

286. The goal, purpose, and/or effect of the Watson reverse-payment agreement was to maintain, enhance, and extend the Brand Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Watson reverse-payment agreement was intended to and did prevent and/or delay generic competition to Bystolic and enabled the Brand Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

287. Forest, Allergan, AbbVie and Watson knowingly and intentionally conspired to maintain, enhance, and extend the Brand Defendants' monopoly power in the relevant market.

288. Forest, Allergan, AbbVie and Watson specifically intended that the reverse-payment agreement would maintain the Brand Defendants' monopoly power in the relevant market, and injure Plaintiffs thereby.

289. Forest, Allergan, AbbVie and Watson each committed at least one overt act in furtherance of the conspiracy.

290. As a direct, proximate, foreseeable, and intended result of Forest's, Allergan's, AbbVie's and Watson's concerted monopolistic conduct, as alleged herein, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power and Plaintiffs were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Watson would have launched its generic version of Bystolic at risk upon receiving final FDA approval, or after a litigation victory, or via a settlement agreement pursuant to which the Brand Defendants and Watson would have agreed to an entry date not delayed by the unlawful Watson reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Forest and Watson would also have applied to any earlier-settling Generic Defendant.

#### **XXIV. CLAIM FIFTEEN**

##### **VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (MONOPOLIZATION AND MONOPOLISTIC SCHEME)**

291. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 178 above. This claim is asserted against Defendants Forest, Allergan and AbbVie.

292. At all relevant times prior to September 17, 2021, the Brand Defendants possessed substantial market power (*i.e.*, monopoly power) in the relevant market. The Brand Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

293. By entering into the reverse-payment agreements with the Generic Defendants, as described above, Forest, Allergan and AbbVie willfully and intentionally maintained, enhanced, and extended their monopoly power using restrictive or exclusionary conduct, rather than by means of a superior product, business acumen, or historic accident, and injured Plaintiffs. Specifically, the Brand Defendants (a) allocated to themselves 100% of the market for neбиволол

HCl in all strengths in the United States until September 17, 2021; (b) delayed the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for nebivolol HCl.

294. It was the Brand Defendants' conscious objective to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

295. The Brand Defendants' anticompetitive conduct substantially harmed competition and maintained the Brand Defendants' monopoly in the relevant market, as alleged herein.

296. As a direct, proximate, foreseeable, and intended result of their illegal and monopolistic conduct, the Brand Defendants unlawfully maintained, enhanced, and extended their monopoly power, and Plaintiffs and their assignors were overcharged and will continue to be overcharged as a result, as alleged herein.

## **XXV. PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment against all Defendants, jointly and severally where appropriate, and for the following relief:

A. A declaration that the conduct alleged above is in violation of sections 1 and 2 of the Sherman Act;

B. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled as provided by law;

C. Permanent injunctive relief enjoining and restraining Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior unlawful conduct;

D. An award of Plaintiffs' costs and reasonable attorneys' fees; and

E. Such other and further relief as the Court may deem just and proper.

**XXVI. JURY TRIAL DEMAND**

Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: December 2, 2020

Respectfully submitted,

s/ Alexander J. Egerváry

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\**Pro hac vice* motion forthcoming.